DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g2030d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

December 6, 2001

Kerry Carmody
Operations Director of Ancillary Services
Providence Holy Cross Medical Center
Out-Patient Diagnostic Center
11570 Indian Hills Street
Mission Hills, CA 91345-1238

W/L Number: 19 - 02
Inspection ID: 1168220008
CFN: 20-29,558
FEI: 1000518880

Dear Kerry Carmody:

We are writing to you because on November 28, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Processor quality control (QC) records in the month of May 2001 were missing for eight (8) operating days (which is 35% of the time) for processor #1 (a [redacted] machine, model [redacted]) which is located in the darkroom.

- Level 1: Processor QC records were missing at least 5 consecutive days for processor #1 (a [redacted] machine; model [redacted]) which is located in the darkroom.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

- Level 2: Corrective actions for processor QC failures were not documented at least once for processor #1 (a [redacted] machine; model [redacted]) which is located in the darkroom.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O.

Box 6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have more specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director

cc:

Ms Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
Standards & Accreditation Dept.
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